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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/035,708 03/05/98 ZEMLAN

F 1259-064

EXAMINER

HM12/0816

HAYES, R

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ART UNIT

PAPER NUMBER

1647

17

DATE MAILED:

08/16/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/035,708

Applicant(s)  
Zemlan et al

Examiner  
Robert C. Hayes

Group Art Unit  
1647



☒ Responsive to communication(s) filed on May 24, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-15, 17-27, 29, and 30 is/are pending in the application.

Of the above, claim(s) 1-13, 21, and 22 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 14, 15, 17-20, 23-27, 29, and 30 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-15, 17-27, 29, and 30 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner. - *NOT signed*

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ *Correction of CRF*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 5/24/00 has been entered.
2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
3. The rejection of claims 17-20, 25, 27 & 29 under 35 U.S.C. 112, first paragraph, as based on a disclosure that is critical or essential to the practice of the invention, is withdrawn due to the amendment of the specification to incorporate the essential material.
4. Applicant's arguments filed 5/24/00 have been fully considered but they are not deemed to be persuasive.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 14-15, 17-20, 23-27 & 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception within context of that disclosed within the specification, at the time of filing the instant application, is apparent for the recitation, "derivatives thereof" of the tau protein of Goedert, or fragments thereof (i.e., SEQ ID NO:1); thereby, constituting new matter.

7. Claims 14-15, 17-20, 23-27 & 29-30 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of assaying axonal damage of the CNS through identification of tau degradation products comprising ser199-ser396 of the human tau sequence disclosed in Goedert et al (1989) (i.e., SEQ ID NO:1) in the CSF, using deposited cTau-7, cTau-8 and cTau-12 Mabs, does not reasonably provide enablement for methods of determining axonal damage using structurally unknown and uncharacterized monoclonal antibodies, or for assaying structurally uncharacterized "derivatives or fragments" of a tau protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in paper #12, and as follows.

In contrast to Applicants' assertions on pages 6-7 of the response, an invitation for others to obtain the required components to practice the instant invention does not enable the instant

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invention, by definition, because it requires undue experimentation for the skilled artisan to discover how to make and use the current invention; consistent with the teachings of Geysen et al. previously made of record (i.e., as it relates to the recitation, "derivatives and fragments thereof").

8. Claims 19-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in paper # 12 and as follows.

"Derivatives thereof" defines no reference sequence (i.e., tau SEQ ID NO) for determining what constitutes a given position number for serine; thereby, still making the claims ambiguous.

9. Claims 17-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No proper antecedent basis exists for "said *at least one isoform* of said tau protein" in base claim 14. It is suggested that amending the claim to "wherein said... axonally-derived protein is (some defined) fragment of the tau protein of SEQ ID NO:1" may obviate this particular rejection.

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10. Claims 14-15, 17-20, 23-27 & 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandermeeren et al (WO 94/13795), for the reasons made of record in paper # 12, and as follows.

In contrast to Applicants' assertions on pages 8-10 of the response, Vandermeeren et al. teach all structural limitations of "(a) obtaining CSF..." and "(b) treating said sample of CSF with at least one monoclonal antibody...", as recited in the claims. Any alleged primary intended purpose of Vandermeeren's method that relates to detecting "tau inclusion bodies in patients" is immaterial to whether the claims encompass the teachings disclosed by Vandermeeren, in which tau is an "axonally-derived protein", by definition. As previously made of record, Vandermeeren et al. specifically disclose that tau "is abundantly present in the axonal compartment of these neurons", and that CNS basal forebrain cholinergic neurons/axonal processes are well known to degenerate in Alzheimer's disease. Therefore, measurement of tau protein with a monoclonal antibody is inherently an indicator of "determining axonal damage in the human CNS", for the reasons made of record; especially in light of the well known Wallerian degeneration that accompanies axonal degeneration after nerve damage.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

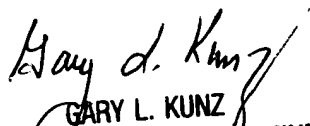
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
August 10, 2000

  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600